K073415

MAY 23 2008

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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Date: December 3, 2007

807.92(a)(2)

Trade Names: Nemus System
Nemus PC Peripheral

Common Name: Electromyograph

Classification Name(s): Electromyograph

Classification Number: IKN

807.92(a)(3)

Predicate Device(s)

Esaote Biomedica	PHASIS	K922488
Oxford Instruments PLC	Sinergy LT	K981405

Additional Substantial Equivalence Information is provided in the following Substantial Equivalence Comparison Table.

510(k) Summary
EB Neuro, S.p.A.
Nemus

807.92 (a)(4)

Device Description

There are two configurations of NeMus: NeMus System and NeMus PC Peripheral.

The "Nemus system" is a complete system provided with a cart (expressly designed for this device and equipped with isolation transformer, the base unit support mobile arm, places for computer, keyboard, footswitch, printer, and dedicated keyboard and so on. The complete system provided of all the part ordered by the customer is completely wired, assembled and tested in factory before to ship to the final user. Like the hardware parts, all the needed software is installed and configured in factory.

The "Nemus PC Peripheral" is a base kit (constituted by the NeMus 1 Amplifier the AC/DC adapter, cables and GALILEO NT management software) which, by adding a Personal Computer, becomes a digital electromiograph system. This configuration is developed and verified in order to allow a Distributor or the User to "build" an acquisition/processing EMG signal system by using the NeMus 1 acquisition module, the GALILEO_NT/MYTOWIN management software and their own Personal Computer (and peripherals). However the PC must be compliant with EBNeuro specified minimum requirements. Of course the "system builder" must follow all the indications detailed in the related User Manual provided with the system. In this kind of system configuration, the "base kit" provided by EBNeuro is a sort of "peripheral" of a PC system. This configuration allows the Distributor or the User to use its own PC, cart or other "system" arrangement of its choice.

NeMus systems are diagnostic medical systems able to detect the electric signals produced by the peripheral nerve system and by skeletal muscles.

The Nemus system is intended to monitor, record and display the bioelectric signal produced by the muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular diseases (EMG). The device may use electrical stimulus, visual stimulus or sound stimulus for use in evoked response measurements (EP).

807.92(a)(5)

Intended Use(s)

NEMUS systems are diagnostic medical systems able to detect the electric signals produced by the peripheral nerve system and by skeletal muscles.

The NEMUS system is intended to monitor, record and display the bioelectric signal produced by the muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular diseases (EMG). The device may use electrical stimulus or sound stimulus for use in evoked response measurements (EP).

Technological Characteristics

Substantial Equivalence Comparison Table

Product Characteristic	Nemus System (submission device)	PHASIS (predicate device)	Sinergy LT
Regulatory			
Manufacturer	EBNeuro S.p.A.	Esaote Biomedica	Oxford Instruments plc
510(k) number	Not assigned	K922488	K981405
Device class	Class II	Class II	Class II
Product code	IKN	IKN	GMF
Device type	Electromyograph	Electromyograph	Stimulator, Electrical, Evoked response
Regulation Number	890.1375	890.1375	882.1870

Product Characteristic	Nemus System (submission device)	PHASIS (predicate device)	Sinergy LT
Labeling			
Intended use	The NEMUS system is intended to monitor, record and display the bioelectric signal produced by the muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular diseases (EMG). The device may use electrical stimulus or sound stimulus for use in evoked response measurements (EP).	The PHASIS electomyograph is intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor and display the electrical activity produced by nerves for the diagnosis and prognosis of neuromuscular disease	2 channel electromyograph which provides facilities for EMG and Evoked Potentials testing for a range of clinical application. Synergy LT is designed to enable reliable recording display and documentation of electrophysiological information from the human nervous and muscular system in a clinical environment.
Warnings	Items related to off-label use.	Items related to off-label use.	Items related to off-label use.
Contraindication	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics.
Target population	Pediatric through adult	Pediatric through adult	Pediatric through adult
Environment of use	Hospitals, institutions, or other test environments.	Hospitals, institutions, or other test environments	Hospitals, institutions, or other test environments
Prescription status	Available only on the order of a physician.	Available only on the order of a physician.	Available only on the order of a physician.
User Service	No user service allowed	No user service allowed	No user service allowed

Product Characteristic	Nemus System (submission device)	PHASIS (predicate device)	Sinergy LT
Design - General			
General system approach	Computer based equipment with dedicated hardware peripherals/components	Computer based equipment with dedicated hardware peripherals/components	Computer based equipment with dedicated hardware peripherals/components
User input device	Microsoft Windows mouse/keyboard driven graphic interface. Dedicated external keyboard (optional)	ASCII keyboard with application specific function key. Re-definable "soft" keys with on-screen indication	Microsoft Windows mouse/keyboard driven graphic interface.
User output device	Digital color display Commercial printers	Digital color display Commercial printers	Digital color display Commercial printers
Patient inputs	2 channels preamplifiers, isolated	2-4 channels preamplifiers, isolated	2 channels preamplifiers, isolated
Signal acquisition	Analog-to-digital conversion at variable sampling rate	Analog-to-digital conversion at variable sampling rate	Analog-to-digital conversion at variable sampling rate
Trigger input (synchronization to external events)	YES	YES	YES
Trigger output (synchronization for external devices)	YES	YES	YES
Footswitch for hands-free operation	YES (optional)	YES	YES
Use of standard software platform (Operating System)	YES – Microsoft Windows	YES – Motorola Versados	YES – Microsoft Windows
Customization of clinical protocols	Via storage / retrieval of user-defined settings	Via storage / retrieval of user-defined settings	Via storage / retrieval of user-defined settings
Application flexibility / expandability	Via software update	Via software update	Via software update
Safety Standards	IEC 60601-1 IEC 60601-1-1 IEC 60601-2-26	IEC 60601-1	IEC 60601-1

	IEC 60601-2-40 IEC 60601-1-2		
Patient circuitry isolation	optic	optic	optic
System Components	Nemus 1 Base Unit (Amplifier) Host Computer (PC) Printer (optional) Cart (optional) Dedicated Keyboard (optional)	Headbox (Amplifier) Computer Cart Printer (optional)	Headbox (Amplifier) Computer (PC) Cart Printer (optional)
Amplifier-Computer interface	LAN Ethernet 100 Mbit	proprietary	proprietary
System Power Supply	From mains (110-240 VAC) trough isolation transformer	From mains (110-240 VAC)	From mains (110-240 VAC)
Amplifier Power Supply	15 VDC from medical approved AC/DC converter	Internal power supply	Internal power supply
Size (H/W/D) mm	Nemus System : 1250/750/850 (complete system, with cart, monitor, arm)	238/457/413	500/209/321 (cart : 720/640/780)
Weight (complete system – kg)	Nemus System : 90 (complete system, with cart, monitor, arm)	80 (with cart)	55 (with cart)

Product Characteristic	Nemus System (submission device)	PHASIS (predicate device)	Sinergy LT
Design - Acquisition			
Number of channels	2	2/4	2
CMRR	>100 dB	>100 dB	> 110 dB
Noise	< 0.3 µVrms (0.1 – 00 Hz) < 20 nV/ Hz ½ (10 Hz – 10 kHz)	<0.9 µVrms (0.1 Hz – 10 kHz)	<0.7 µVrms (0.1 Hz – 10 kHz)
Input impedance	> 1000 MOhm / 8 pF	> 100 MOhm / 15 pF	> 1000 MOhm / 30 pF
Low pass filter	20 Hz – 16 kHz (15 step)	10 Hz – 20 KHz (11 step)	50 Hz – 16 kHz (10 step)
High pass filter	0.01 – 500 Hz (11 step)	0.01– 500 Hz (13 step)	DC, 30 – 2000 Hz
Notch filter	50/60 Hz selectable	50/60 Hz selectable	50/60 Hz selectable
A/D conversion	24 bit Sigma-Delta	16 bit	16 bit
Sampling rate	4.194 MHz	0.5 µs max	50 kHz
Analysis time	5 ms – 10 s	1 ms – 20 s	5 ms – 10s
Time base	Single	Single, dual	single
Trigger mode	Free, Auto, Internal, External	Recurrent, manual, self, external	Auto, Internal, External
Signal delay (pre/post)	0-5 div	0-5 div	0 -9 div
Ohmmeter	0-100 kOhm (auto full scale)	0-100 kOhm (auto full scale)	0 – 32 kOhm

Product Characteristic	Nemus System (submission device)	PHASIS (predicate device)	Sinergy LT
Design - Stimulators			
Somatosensory (electrical) Stimulator	Type: *constant current* N. output : 1 Max output : *100 mA* Pulse width: *0.05 – 1ms* Mode: *single, train*	Type: *constant current/voltage* N. output : *1* Max output:*100 mA* Pulse width: *0.01 – 1 ms* Mode: *single, recurrent, paired, trains*	Type: *constant current/voltage* N. output : 1 Max output: 100 mA Pulse width: 0.05-1 ms Mode: *single, double, train*
Audio Stilmulator	Output mode: *click, tone* Sound pressure: *0-132 dB SPL* Phase: *condens., raref., alternate* Signal frequency: *125-8000 Hz* Plateau time: *1-200 ms* Rise/fall time: *1-100 ms* Mask level: *-40 - +10 dB (relative)* Click width: *1-100 µs* Stimulus presen. *Left, right, binaural* Headset: *TDH 39*	Output mode: *click, pip, tone* Sound pressure:*20-132 dB SPL* Phase: *condens., raref., alternate* Signal frequency: *125-8000 Hz* Plateau time: *0-200 ms* Rise/fall time: *0-200 ms* Mask level: *0-90 dB* Click width: *50-500 µs* Stimulus presen. *Left, right, binaural* Headset: *TDH 50P*	Output mode: *click, pip, tone* Sound pressure: *0-122 dB SPL* Phase: *condens., raref., alternate* Signal frequency: *125-8000 Hz* Plateau time: *1-999 ms* Rise/fall time: *1-255 ms* Mask level: *-40 - +10 dB (relative)* Click width: *0.05-1ms* Stimulus presen. *Left, right, binaural* Headset: *TDH 39*
Basic EMG application modules : Free run acquisition Nerve conduction study Self triggered acquisition Spontaneous activity Single fiber EMG Motor Unit Analysis F wave analysis	 YES YES YES YES YES YES YES	 YES YES YES YES YES YES YES	 YES YES YES YES YES YES YES
Basic EP application modules Somatosensory EP Auditory EP	 YES YES	 YES YES	 YES YES

Visual EP (flash) Visual EP (pattern)	NO NO	YES YES	YES YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Eb Neuro S.p.A
% The Anson Group
Ms. Allison Scott
Official Correspondent
11460 North Meridian Street, Suite 150
Carmel, Indiana 46032

Re: K073415
Trade/Device Name: Nemus System and Nemus PC Peripheral
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic Electromyograph
Regulatory Class: Class II
Product Code: IKN, GWF, GWJ, JXE
Dated: May 9, 2008
Received: May 12, 2008

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: NeMus system & NeMus PC Peripheral

Indications For Use:

NEMUS systems are diagnostic medical systems able to detect the electric signals produced by the peripheral nerve system and by skeletal muscles.

The NEMUS system is intended to monitor, record and display the bioelectric signal produced by the muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular diseases (EMG). The device may use electrical stimulus or sound stimulus for use in evoked response measurements (EP).

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for MAM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073415